K122031 #1/2

OCT 9 2012

510(k) Summary
(Per 21 CFR 807.92)

General Company Information:	Nextremity Solutions, Inc. Arthur A. Alfaro President/CEO 167 Stone Hill Road Colts Neck, NJ 07722 Phone: (732) 683-9304 Fax: (732) 683-9476
Date Prepared	July 9, 2012
General Device Information	
Product Name:	Nextra™ Ti Hammertoe Correction System
Classification:	Smooth or threaded bone fixation fasteners, Product code: HWC - Class II
Predicate Devices	
Nextremity Solutions, LLC	FlexFusion™ Fixation implant [510(k) K110445]
Arthrex, Inc.	Arthrex Bio-Pin (Marketed as Arthrex Trim-It™ Spin Pin) [510(k) K050259]

Description

The Nextremity Solutions Nextra™ Ti Hammertoe Correction (Nextra) System consists of proximal and distal components provided as a set with the necessary surgical site preparation and insertion instruments in a procedure pack. Nextra is fabricated from medical grade titanium alloy (6Al-4V) and the design allows the clinician to establish a natural angulation of the fused inter-digital joint.

Intended Use (Indications)

The Nextra™ Ti Hammertoe Correction System is indicated for small bone reconstruction limited to inter-digital repair and fusion of the lesser toes.

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Substantial Equivalence

The Nextra™ Ti Hammertoe Correction System possesses the same technologic characteristics of the predicate devices. These characteristics include the intended use, basic design, material, size and fundamental technology.

Performance Data

Mechanical testing was performed as described in relevant recognized standards, including testing for pull-out force, driving torque, torque to failure, static and dynamic flexion extension resistance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Nextremity Solutions, LLC
% Mr. Arthur A. Alfaro
President, Chief Executive Officer
167 Stone Hill Road
Colts Neck, New Jersey 07722

OCT 9 2012

Re: K122031
Trade/Device Name: Nextra™ Ti Hammertoe Correction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 9, 2012
Received: June 11, 2012

Dear Mr. Alfaro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122031

Device Name: Nextremity Solutions, Nextra™ Ti Hammertoe Correction System

Indications For Use:

The Nextra™ Ti Hammertoe Correction System is indicated for small bone reconstruction limited to inter-digital repair and fusion of the lesser toes.

Prescription Use ____X_____ **AND/OR** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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